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<b>SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (Use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	10/725,009
				Filing Date	December 2, 2003
				First Named Inventor	GEALL, Andrew
				Art Unit	1645
				Examiner Name	HINES, Jana A.
Sheet	1	of	1	Attorney Docket Number	1530.0620001/EJH/UWJ

U.S. PATENT DOCUMENTS					
Examiner Initials <sup>1</sup>	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	AJ3	5,709,879	01/20/1998	Barchfeld <i>et al.</i>	
	AK3	5,994,314	11/30/1999	Wheeler	
	AA4	5,994,317	11/30/1999	Wheeler	
	AB4	6,147,055	11/14/2000	Hobart <i>et al.</i>	
	AC4	6,248,363 B1	06/19/2001	Patel <i>et al.</i>	
	AD4	6,251,599 B1	06/26/2001	Chen <i>et al.</i>	
	AE4	6,359,054 B1	03/19/2002	Lemieux <i>et al.</i>	
	AF4	6,482,518 B1	11/19/2002	Short <i>et al.</i>	
	AG4	2003/0032615 A1	02/13/2003	Felgner <i>et al.</i>	
	AH4	2003/0186913 A1	10/02/2003	Wolff <i>et al.</i>	
	AI4	2003/0191082 A1	10/09/2003	Wheeler	
	AJ4	2004/0157789 A1	08/12/2004	Geall	
	AK4	6,867,195 B1	03/15/2005	Felgner <i>et al.</i>	
	AA5	6,875,748 B2	04/05/2005	Manthorpe <i>et al.</i>	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)				
	AP2	WO 2001/065911 A2	09/13/2001	Valentis, Inc.		

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NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>	
	NPL-1	BAUMGARTNER, I., <i>et al.</i> , "Constitutive Expression of phVEGF <sub>165</sub> After Intramuscular Gene Transfer Promotes Collateral Vessel Development in Patients With Critical Limb Ischemia," <i>Circulation</i> 97:1114-1123, Lippincott, Williams, & Wilkins (1998)		
	NPL-2	CHEN, Z-Y., <i>et al.</i> , "Linear DNAs Concatemerize <i>in Vivo</i> and Result in Sustained Transgene Expression in Mouse Liver," <i>Mol. Ther.</i> 3:403-410, Academic Press (March 2001)		
	NPL-3	CHENG, S.H., and Scheule, R.K., "Airway delivery of cationic lipid: DNA complexes for cystic fibrosis," <i>Adv. Drug Deliv. Rev.</i> 30:173-184, Elsevier Science B.V. (1998)		
	NPL-4	CHERNG, J.-Y., <i>et al.</i> , "Effect of DNA topology on the transfection efficiency of poly((2-dimethylamino)ethyl methacrylate)-plasmid complexes," <i>J. Control. Release</i> 60:343-353, Elsevier Science B.V. (1999)		
	NPL-5	DALESANDRO, J., <i>et al.</i> , "Gene Therapy for Donor Hearts: Ex Vivo Liposome-Mediated Transfection," <i>J. Thorac. Cardiovasc. Surg.</i> 111:416-422, Mosby-Year Book, Inc. (1996)		
	NPL-6	DANKO, I., <i>et al.</i> , "Dystrophin expression improves myofiber survival in <i>mdx</i> muscle following intramuscular plasmid DNA injection," <i>Hum. Mol. Genet.</i> 2:2055-2061, Oxford University Press (1993)		
	NPL-7	DARQUET, A-M., <i>et al.</i> , "A new DNA vehicle for nonviral gene delivery: supercoiled minicircle," <i>Gene Ther.</i> 4:1341-1349, Nature Publishing Group (1997)		
	NPL-8	DAVIS, H.L., <i>et al.</i> , "Direct gene transfer in skeletal muscle: plasmid DNA-based immunization against the hepatitis B virus surface antigen," <i>Vaccine</i> 12:1503-1509, Butterworth-Heinemann Ltd. (1994)		
	NPL-9	DOW, S.W., <i>et al.</i> , "Systemic and Local Interferon $\gamma$ Gene Delivery to the Lungs for Treatment of Allergen-Induced Airway Hyperresponsiveness in Mice," <i>Hum. Gene Ther.</i> 10:1905-1914, Mary Ann Liebert, Inc. (1999)		
	NPL-10	GRAMZINSKI, R., <i>et al.</i> , "Immune Response to a Hepatitis B DNA Vaccine in <i>Aotus</i> Monkeys: A Comparison of Vaccine Formulation, Route, and Method of Administration," <i>Mol. Med.</i> 4:109-118, The Picower Institute Press (1998)		

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	NPL-11	HARLAND, R., and Misher, L., "Stability of RNA in developing <i>Xenopus</i> embryos and identification of a destabilizing sequence in TFI <sub>II</sub> A messenger RNA," <i>Development</i> 102:837-852, The Company of Biologists Limited (1988)	
	NPL-12	HORTON, H.M., <i>et al.</i> , "A gene therapy for cancer using intramuscular injection of plasmid DNA encoding interferon $\alpha$ ," <i>Proc. Natl. Acad. Sci. USA</i> 96:1553-1558, National Academy of Sciences (1999)	
	NPL-13	LEVY, M.Y., <i>et al.</i> , "Characterization of plasmid DNA transfer into mouse skeletal muscle: evaluation of uptake mechanism, expression and secretion of gene products into blood," <i>Gene Ther.</i> 3:201-211, Nature Publishing Group (1996)	
	NPL-14	MIR, L.M., <i>et al.</i> , "High-efficiency gene transfer into skeletal muscle mediated by electric pulses," <i>Proc. Natl. Acad. Sci. USA</i> 96:4262-4267, National Academy of Sciences (1999)	
	NPL-15	MOFFATT, M., and Cookson, W., "Naked DNA: New shots for allergy?," <i>Nat. Med.</i> 2:515-516, Nature America Inc. (1996)	
	NPL-16	NOVO, F.J., <i>et al.</i> , "Gene transfer and expression of human $\alpha$ -galactosidase from mouse muscle in vitro and in vivo," <i>Gene Ther.</i> 4:488-492, Nature Publishing Group (1997)	
	NPL-17	PELLETIER, J., and Sonenberg, N., "Internal initiation of translation of eukaryotic mRNA directed by a sequence derived from poliovirus RNA," <i>Nature</i> 334:320-325, Macmillan Magazines Ltd. (1988)	
	NPL-18	PICCIRILLO, C.A., and Prud'homme, G.J., "Prevention of Experimental Allergic Encephalomyelitis by Intramuscular Gene Transfer with Cytokine-Encoding Plasmid Vectors," <i>Hum. Gene Ther.</i> 10:1915-1922, Mary Ann Liebert, Inc. (1999)	
	NPL-19	PICCIRILLO, C.A., <i>et al.</i> , "TGF- $\beta$ 1 Somatic Gene Therapy Prevents Autoimmune Disease in Nonobese Diabetic Mice," <i>J. Immunol.</i> 161:3950-3956, The American Association of Immunologists (1998)	
	NPL-20	QIN, L., <i>et al.</i> , "Gene Transfer for Transplantation - Prolongation of Allograft Survival with Transforming Growth Factor- $\beta$ 1," <i>Ann. Surg.</i> 220:508-519, J.B. Lippincott Company (1994)	

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	NPL-21	QIN, Y.-J., <i>et al.</i> , " Gene Suture - A Novel Method for Intramuscular Gene Transfer and its Application in Hypertension Therapy," <i>Life Sci.</i> 65:2193-2203, Elsevier Science Inc. (1999)		
	NPL-22	RAGNO, S., <i>et al.</i> , "Protection of Rats from Adjuvant Arthritis by Immunization with Naked DNA Encoding for Mycobacterial Heat Shock Protein 65," <i>Arthritis Rheum.</i> 40:277-283, American College of Rheumatology (1997)		
	NPL-23	RESTIFO, N.P., <i>et al.</i> , "Enhancing the Recognition of Tumour Associated Antigens," <i>Folia Biologica</i> 40:74-88, Institute of Molecular Genetics (1994)		
	NPL-24	SCHRIJVER, R.S., <i>et al.</i> , "Immunization of cattle with a BHV1 vector vaccine or a DNA vaccine both coding for the G protein of BRSV," <i>Vaccine</i> 15:1908-1916, Elsevier Science Ltd. (1997)		
	NPL-25	TRIPATHY, S.K., <i>et al.</i> , "Long-term expression of erythropoietin in the systemic circulation of mice after intramuscular injection of a plasmid DNA vector," <i>Proc. Natl. Acad. Sci. USA</i> 93:10876-10880, National Academy of Sciences (1996)		
	NPL-26	TSURUMI, Y., <i>et al.</i> , "Direct Intramuscular Gene Transfer of Naked DNA Encoding Vascular Endothelial Growth Factor Augments Collateral Development and Tissue Perfusion," <i>Circulation</i> 94:3281-3290, Lippincott, Williams, & Wilkins (1996)		
	NPL-27	ULMER, J.B., <i>et al.</i> , "Immunization Against Viral Proteins with Naked DNA," <i>Ann. N.Y. Acad. Sci.</i> 772:117-125, New York Academy of Sciences (1995)		
	NPL-28	VAHLSING, H.L., <i>et al.</i> , "Immunization with plasmid DNA using a pneumatic gun," <i>J. Immunol. Methods</i> 175:11-22, Elsevier Science B.V. (1994)		
	NPL-29	YAGI, K., <i>et al.</i> , "Basic Study on Gene Therapy of Human Malignant Glioma by Use of the Cationic Multilamellar Liposome-Entrapped Human Interferon $\beta$ Gene," <i>Hum. Gene Ther.</i> 10:1975-1982, Mary Ann Liebert, Inc. (1999)		

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